

WHAT IS CLAIMED IS:

- 1 1. A method of visually quantifying an amount of an
2 analyte in a sample, wherein the analyte is a member of a
3 specific binding pair (sbp member), comprising:
4 providing a lateral flow matrix which defines a flow
5 path and which comprises in series, a sample receiving zone, a
6 labeling zone, and one or more serially oriented capture
7 zones, wherein the labeling zone comprises a diffusively bound
8 labeled first sbp member that is complementary to ~~or analogous~~
9 ~~to~~ the analyte, and each of the one or more capture zones
10 comprises at least a second sbp member immobilized in the
11 capture zone, the second sbp member being complementary to the
12 analyte;
13 contacting the sample with the sample receiving
14 zone, whereby the sample flows along the flow path;
15 observing a pattern of label that accumulates at the
16 one or more capture zones; and
17 correlating a pattern of label accumulated in the
18 one or more capture zones to the amount of analyte in the
19 sample.
- 1 2. The method of claim 1, wherein the first sbp member
2 is analogous to the analyte.
- 1 3. The method of claim 1, wherein the first sbp member
2 is complementary to the analyte.
- 1 4. The method of claim 1, wherein the labeled first sbp
2 member is an antiligand capable of binding the analyte.
- 1 5. The method of claim 1, wherein the first sbp member
2 includes a visually detectable label.
- 1 6. The method of claim 5, wherein the visually
2 detectable label comprises a visible particulate label.

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1 15. The method of claim 1, wherein the sample receiving
2 zone comprises an amount of a third sbp member immobilized
3 within the sample receiving zone and complementary to the
4 analyte, the amount being sufficient to bind a threshold level
5 of the analyte.

1 16. A method of determining an amount of an analyte in a
2 sample, wherein the analyte is a member of a specific binding
3 pair (sbp member), comprising:

4 providing a lateral flow matrix which defines a flow
5 path and which comprises in series, a sample receiving zone, a
6 labeling zone, and one or more serially oriented capture
7 zones, wherein the labeling zone comprises a diffusively bound
8 labeled first sbp member that is complementary to the analyte,
9 and each of the one or more capture zones comprises at least a
10 second sbp member immobilized in the capture zone, the second
11 sbp member being analogous to the analyte;

12 contacting the sample with the sample receiving
13 zone, whereby the sample flows along the flow path;

14 observing a pattern of labeled first sbp member that
15 accumulates at the one or more capture zones; and

16 correlating a pattern of label accumulated in the
17 one or more capture zones to the amount of analyte in the
18 sample.

1 17. The method of claim 16, wherein the labelled first
2 sbp member is a antibody capable of binding the analyte.

1 18. The method of claim 16, wherein the labelled first
2 sbp member includes a visually detectable label.

1 19. The method of claim 18, wherein the visually
2 detectable label comprises a visible particulate label.

1 20. The method of claim 16, wherein the second sbp
2 member is attached to particles and the particles are
3 immobilized in the one or more capture zones.

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19 correlating a pattern of label accumulated in the
20 one or more capture zones to the amount of analyte in the
21 sample.

1 25. The method of claim 26, wherein the labelled first
2 sbp member is an antibody capable of binding the analyte.

1 26. The method of claim 26, wherein the first sbp member
2 includes a visually detectable label.

1 27. The method of claim 28, wherein the visually
2 detectable label comprises a visible particulate label.

1 28. The method of claim 26, wherein the third sbp member
2 is analogous to the analyte.

1 29. The method of claim 26, wherein the third sbp member
2 is an antibody to the first sbp member.

1 30. The method of claim 26, wherein the third sbp member
2 is attached to particles and the particles are immobilized in
3 the capture zones.

1 31. The method of claim 26, wherein the lateral flow
2 matrix comprises a plurality of capture zones, and the step of
3 observing a pattern of label that accumulates at the one or
4 more capture zones comprises determining a number of capture
5 zones at which label accumulates.

1 32. The method of claim 26, wherein the lateral flow
2 matrix comprises a single capture zone having the second sbp
3 member uniformly immobilized in the single capture zone and
4 the step of observing a pattern of labeled first sbp member
5 that accumulates at the one or more capture zones comprises
6 observing a distance traversed by the label along the single
7 capture zone.

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1 33. The method of claim 26, wherein the barrier zone
2 comprises an amount of the second sbp member sufficient to
3 bind substantially all of the labelled first sbp member when
4 the analyte is present at a concentration below a
5 predetermined threshold concentration.

1 34. The method of claim 26, wherein the sample receiving
2 zone comprises an amount of a third sbp member immobilized
3 within the sample receiving zone and complementary to the
4 analyte, the amount being sufficient to bind a threshold level
5 of the analyte.

1 35. A method of determining an amount of an analyte in a
2 sample, wherein the analyte is a member of a specific binding
3 pair (sbp member), comprising:

4 providing a lateral flow matrix which defines a flow
5 path and which comprises in series, a sample receiving zone, a
6 labeling zone, a barrier zone and one or more serially
7 oriented capture zones, wherein the labeling zone comprises a
8 diffusively bound labeled first specific binding pair member
9 that is analogous to the analyte, the barrier zone comprises a
10 second specific binding pair member that is complementary to
11 the analyte, and each of the one or more capture zones
12 comprises at least a third specific binding pair member
13 immobilized in the one or more capture zones, the third
14 specific binding pair member being complementary to the
15 analyte;

16 contacting the sample with the sample receiving
17 zone, whereby the sample flows along the flow path;

18 observing a pattern of label that accumulates at the
19 one or more capture zones; and

20 correlating a pattern of label accumulated in the
21 one or more capture zones to the amount of analyte in the
22 sample.

1 36. The method of claim 37, wherein the first sbp member
2 includes a visually detectable label.

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1 37. The method of claim 38, wherein the visually
2 detectable label comprises a visible particulate label.

1 38. The method of claim 37, wherein the third sbp is an
2 antibody to the analyte.

1 39. The method of claim 37, wherein the third sbp member
2 is attached to particles and the particles are immobilized in
3 the capture zones.

1 40. The method of claim 37, wherein the lateral flow
2 matrix comprises a plurality of capture zones, and the step of
3 observing a pattern of label that accumulates at the one or
4 more capture zones comprises determining a number of capture
5 zones at which label accumulates.

1 41. The method of claim 37, wherein the lateral flow
2 matrix comprises a single capture zone having the second sbp
3 member uniformly immobilized in the single capture zone and
4 the step of observing a pattern of labeled first sbp member
5 that accumulates at the one or more capture zones comprises
6 observing a distance traversed by the label along the single
7 capture zone.

1 42. The method of claim 37, wherein the second sbp
2 member is present within the barrier zone in an amount
3 sufficient to bind a threshold amount of the analyte.

1 43. The method of claim 37, wherein the sample receiving
2 zone comprises an amount of a third sbp member immobilized
3 within the sample receiving zone and complementary to the
4 analyte, the amount being sufficient to bind a threshold level
5 of the analyte.

1 44. A method of determining an amount of an analyte in a
2 sample, wherein the analyte is a member of a specific binding
3 pair (sbp member), comprising:

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4 providing a lateral flow matrix which defines a flow
5 path and which comprises in series, a sample receiving zone,
6 a labeling zone and at least first and second serially
7 oriented capture zones, wherein the labeling zone comprises a
8 diffusively bound labeled first sbp member that is
9 complementary to the analyte whereby the first sbp member and
10 the analyte form an analyte-first sbp member complex, the
11 first capture zone comprises a second sbp member immobilized
12 therein which is capable of binding the analyte-first sbp
13 member complex with a first affinity, and the second capture
14 zone comprises a third sbp member that is capable of binding
15 the analyte-first sbp member complex with a second affinity,
16 the second affinity being different from the first affinity;
17 contacting the sample with the sample receiving
18 zone, whereby the sample flows along the flow path;
19 observing a pattern of label that accumulates at the
20 one or more capture zones; and
21 correlating a pattern of label accumulated in the
22 one or more capture zones to the amount of analyte in the
23 sample.

1 45. The method of claim 46, wherein the labeled first
2 sbp member is an antibody capable of binding the analyte.

1 46. The method of claim 46, wherein the first sbp member
2 includes a visually detectable label.

1 47. The method of claim 48, wherein the visually
2 detectable label comprises a visible particulate label.

1 48. The method of claim 46, wherein at least one of the
2 second and third sbp members is an antibody to the analyte.

1 49. The method of claim 46, wherein at least one of the
2 second and third sbp members is capable of binding the first
3 sbp member.

1 50. The method of claim 46, wherein at least one of the
2 second and third sbp members is an antibody to the first sbp
3 member.

1 51. The method of claim 46, wherein the lateral flow
2 matrix comprises a barrier zone between the labeling zone and
3 the one or more capture zones, the barrier zone comprising a
4 fourth sbp member immobilized thereon, the fourth sbp member
5 being analogous to the analyte.

1 52. The method of claim 46, wherein the sample receiving
2 zone comprises an amount of a fourth sbp member immobilized
3 within the sample receiving zone and complementary to the
4 analyte, the amount being sufficient to bind a threshold level
5 of the analyte.

1 53. A device for determining an amount of an analyte in
2 a sample, wherein the analyte is a member of a specific
3 binding pair (sbp member), comprising a lateral flow matrix
4 which defines a flow path and which comprises in series:
5 a sample receiving zone;
6 a labeling zone; and
7 one or more serially oriented capture zones;
8 wherein the labeling zone comprises a diffusively bound
9 labeled first sbp member that is complementary to ~~or analogous~~
10 ~~to~~ the analyte, and each of the one or more capture zones
11 comprises at least a second sbp member immobilized in the
12 capture zone, the second sbp member being complementary to the
13 analyte.

1 54. The device of claim 55, wherein the first sbp member
2 is analogous to the analyte.

1 55. The device of claim 55, wherein the first sbp member
2 is complementary to the analyte.

a 1 56. The device of claim ⁵³ 55, wherein the labeled first
2 sbp member is an antibody capable of binding the analyte.

a 1 57. The device of claim ⁵³~~55~~, wherein the first sbp member
2 includes a visually detectable label.

a 1 58. The device of claim ⁵⁷~~59~~, wherein the visually
2 detectable label comprises a visible particulate label.

a 1 59. The device of claim ⁵³~~55~~, wherein the second sbp
2 member is attached to particles and the particles are
3 immobilized in the capture zones.

a 1 60. The device of claim ⁵³~~55~~, wherein the second sbp
2 member is an antibody capable of binding the analyte.

a 1 61. The device of claim ⁵³~~55~~, wherein the second sbp
2 member is labelled with a ligand and is immobilized on the
3 capture zone by a receptor for the ligand coimmobilized on the
4 capture zone.

1 62. The device of claim ~~55~~, wherein the second sbp
2 member is an antibody against a complex formed between the
3 analyte and the first sbp member.

a 1 63. The device of claim ⁵³~~55~~, wherein the analyte is a
2 polyepitopic molecule and the first and second sbp members are
3 antibodies against different epitopes of the analyte.

1 64. The device of claim ~~63~~, wherein the ligand is a
2 hapten and the receptor is a complement to the hapten.

a 1 65. The device of claim ⁵³~~55~~, wherein the analyte is human
2 IgE.

a 1 66. The device of claim ⁶⁵~~67~~, wherein the first sbp member
2 is goat anti-human IgE and the second sbp member is mouse
3 monoclonal anti-human IgE.

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67. The device of claim ⁵³~~55~~, wherein the lateral flow matrix comprises a plurality of spatially separated capture zones.

68. The device of claim ⁵³~~55~~, wherein the lateral flow matrix comprises a single capture zone having the second sbp member uniformly immobilized in the single capture zone.

69. The device of claim ~~55~~, wherein the sample receiving zone comprises an amount of a third sbp member immobilized within the sample receiving zone and complementary to the analyte, the amount being sufficient to bind a threshold level of the analyte.

70. The device of claim ⁵³~~55~~, wherein the device comprises a plurality of discrete lateral flow matrices.

71. The device of claim ⁷⁰~~72~~, wherein the plurality of discrete lateral flow matrices have a common sample receiving zone, whereby a sample deposited in the sample receiving zone flows along each of the lateral flow matrices.

72. A device for determining an amount of an analyte in a sample, wherein the analyte is a member of a specific binding pair (sbp member), the device comprising a lateral flow matrix which defines a flow path and which comprises in series:

a sample receiving zone;

a labeling zone; and

one or more serially oriented capture zones;

wherein the labeling zone comprises a diffusively bound labeled first sbp member that is complementary to the analyte, and each of the one or more capture zones comprises at least a second sbp member immobilized in the capture zone, the second sbp member being analogous to the analyte.

73. The device of claim ⁷²~~74~~, wherein the labelled first sbp member is an antibody capable of binding the analyte.

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a 1 74. The device of claim ~~74~~⁷², wherein the labelled first
2 sbp member includes a visually detectable label.

1 75. The device of claim ⁷⁴~~76~~, wherein the visually
2 detectable label comprises a visible particulate label.

a 1 76. The device of claim ⁷²~~74~~, wherein the second sbp
2 member is attached to particles and the particles are
3 immobilized in the one or more capture zones.

a 1 77. The device of claim ⁷²~~74~~, wherein the lateral flow
2 matrix comprises a plurality of capture zones.

a 1 78. The device of claim ⁷²~~74~~, wherein the lateral flow
2 matrix comprises a single capture zone having the second sbp
3 member uniformly immobilized in the single capture zone.

79. The device of claim 74, wherein the sample receiving zone comprises an amount of a third sbp member immobilized within the sample receiving zone and complementary to the analyte, the amount being sufficient to bind a threshold level of the analyte.

a 1 80. The device of claim ⁷²~~71~~, wherein the device comprises
2 a plurality of discrete lateral flow matrices.

a 1 81. The device of claim ³⁰~~82~~, wherein the plurality of
2 discrete lateral flow matrices have a common sample receiving
3 zone, whereby a sample deposited in the sample receiving zone
4 flows along each of the lateral flow matrices.

1 82. A device for determining an amount of an analyte in
2 a sample, wherein the analyte is a member of a specific
3 binding pair (sbp member), the device comprising a lateral
4 flow matrix which defines a flow path and which comprises in
5 series:

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6         a sample receiving zone;
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7 a labeling zone;
8 a barrier zone; and
9 one or more serially oriented capture zones;
10 wherein the labeling zone comprises a diffusively bound
11 labeled first sbp member that is complementary to the analyte,
12 the barrier zone comprises a second sbp member analogous to
13 the analyte immobilized in the barrier zone, and each of the
14 one or more capture zones comprises at least a third sbp
15 member immobilized in the one or more capture zones, the third
16 sbp member being capable of binding the first sbp member.

1 83. The device of claim 84, wherein the labelled first
2 sbp member is an antibody capable of binding the analyte.

1 84. The device of claim 84, wherein the first sbp member
2 includes a visually detectable label.

1 85. The device of claim 86, wherein the visually
2 detectable label comprises a visible particulate label.

1 86. The device of claim 84, wherein the third sbp member
2 is analogous to the analyte.

1 87. The device of claim 84, wherein the third sbp member
2 is an antibody to the first sbp member.

1 88. The device of claim 84, wherein the third sbp member
2 is attached to particles and the particles are immobilized in
3 the capture zones.

1 89. The device of claim 84, wherein the lateral flow
2 matrix comprises a plurality of capture zones.

1 90. The device of claim 84, wherein the lateral flow
2 matrix comprises a single capture zone having the second sbp
3 member uniformly immobilized in the single capture zone.

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1 91. The device of claim 84, wherein the barrier zone
2 comprises an amount of the second sbp member sufficient to
3 bind substantially all of the labelled first sbp member when
4 the analyte is present at a concentration below a
5 predetermined threshold concentration.

1 92. The device of claim 84, wherein the sample receiving
2 zone comprises an amount of a third sbp member immobilized
3 within the sample receiving zone and complementary to the
4 analyte, the amount being sufficient to bind a threshold level
5 of the analyte.

1 93. The device of claim 84, wherein the device comprises
2 a plurality of discrete lateral flow matrices.

1 94. The device of claim 95, wherein the barrier zone in
2 each of said plurality of discrete lateral flow matrices
3 comprises a different amount of the second sbp member,
4 sufficient to bind a different amount of the labeled first sbp
5 member.

1 95. The device of claim 95, wherein the plurality of
2 discrete lateral flow matrices have a common sample receiving
3 zone, whereby a sample deposited in the sample receiving zone
4 flows along each of the lateral flow matrices.

1 96. A device for determining an amount of an analyte in
2 a sample, wherein the analyte is a member of a specific
3 binding pair (sbp member), the device comprising a lateral
4 flow matrix which defines a flow path and which comprises in
5 series:

6 a sample receiving zone;

7 a labeling zone;

8 a barrier zone; and

9 one or more serially oriented capture zones;

10 wherein the labeling zone comprises a diffusively bound

11 labeled first specific binding pair member that is analogous
12 to the analyte, the barrier zone comprises a second specific

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13 binding pair member that is complementary to the analyte, and
14 each of the one or more capture zones comprises at least a
15 third specific binding pair member immobilized in the one or
16 more capture zones, the third specific binding pair member
17 being complementary to the analyte.

1 97. The device of claim 98, wherein the first sbp member
2 includes a visually detectable label.

1 98. The device of claim 99, wherein the visually
2 detectable label comprises a visible particulate label.

1 99. The device of claim 98, wherein the third sbp is an
2 antibody to the analyte.

1 100. The device of claim 98, wherein the third sbp member
2 is attached to particles and the particles are immobilized in
3 the capture zones.

1 101. The device of claim 98, wherein the lateral flow
2 matrix comprises a plurality of capture zones.

1 102. The device of claim 98, wherein the lateral flow
2 matrix comprises a single capture zone having the second sbp
3 member uniformly immobilized in the single capture zone.

1 103. The device of claim 98, wherein the second sbp
2 member is present within the barrier zone in an amount
3 sufficient to bind a threshold amount of the analyte.

1 104. The device of claim 98, wherein the sample receiving
2 zone comprises an amount of a third sbp member immobilized
3 within the sample receiving zone and complementary to the
4 analyte, the amount being sufficient to bind a threshold level
5 of the analyte.

1 105. The device of claim 98, wherein the device comprises
2 a plurality of discrete lateral flow matrices.

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1 106. The device of claim 107, wherein the barrier zone in
2 each of said plurality of discrete lateral flow matrices
3 comprises a different amount of the second sbp member,
4 sufficient to bind a different amount of the analyte.

1 107. The device of claim 107, wherein the plurality of
2 discrete lateral flow matrices have a common sample receiving
3 zone, whereby a sample deposited in the sample receiving zone
4 flows along each of the lateral flow matrices.

1 108. A device for determining an amount of an analyte in
2 a sample, wherein the analyte is a member of a specific
3 binding pair (sbp member), the device comprising a lateral
4 flow matrix which defines a flow path and which comprises in
5 series:

6 a sample receiving zone;

7 a labeling zone; and

8 at least first and second serially oriented capture
9 zones;

10 wherein the labeling zone comprises a diffusively bound
11 labeled first sbp member that is complementary to the analyte
12 whereby the first sbp member and the analyte form an analyte-
13 first sbp member complex, the first capture zone comprises a
14 second sbp member immobilized therein which is capable of
15 binding the analyte-first sbp member complex with a first
16 affinity, and the second capture zone comprises a third sbp
17 member that is capable of binding the analyte-first sbp member
18 complex with a second affinity, the second affinity being
19 different from the first affinity.

1 109. The device of claim 110, wherein the labeled first
2 sbp member is an antibody capable of binding the analyte.

1 110. The device of claim 110, wherein the first sbp
2 member includes a visually detectable label.

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1 111. The device of claim 112, wherein the visually
2 detectable label comprises a visible particulate label.

1 112. The device of claim 110, wherein at least one of the
2 second and third sbp members is an antibody to the analyte.

1 113. The device of claim 110, wherein at least one of the
2 second and third sbp members is capable of binding the first
3 sbp member.

1 114. The device of claim 110, wherein at least one of the
2 second and third sbp members is an antibody to the first sbp
3 member.

1 115. The device of claim 110, wherein the lateral flow
2 matrix comprises a barrier zone between the labeling zone and
3 the one or more capture zones, the barrier zone comprising a
4 fourth sbp member immobilized thereon, the fourth sbp member
5 being analogous to the analyte.

1 116. The device of claim 110, wherein the sample
2 receiving zone comprises an amount of a fourth sbp member
3 immobilized within the sample receiving zone and complementary
4 to the analyte, the amount being sufficient to bind a
5 threshold level of the analyte.

1 117. The device of claim 110, wherein the device
2 comprises a plurality of discrete lateral flow matrices.

1 118. The device of claim 119, wherein the barrier zone in
2 each of said plurality of discrete lateral flow matrices
3 comprises a different amount of the second sbp member,
4 sufficient to bind a different amount of the analyte.

1 119. The device of claim 119, wherein the plurality of
2 discrete lateral flow matrices have a common sample receiving
3 zone, whereby a sample deposited in the sample receiving zone
4 flows along each of the lateral flow matrices.

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1 120. A kit for determining an amount of an analyte in a
2 sample, wherein the analyte is a member of a specific binding
3 pair (sbp member), the kit comprising the device of any one of
4 claims 55, 74, 84, 98 or 110, a chart for correlating an
5 observed accumulation of label at the one or more capture
6 zones, to a concentration of analyte in a sample applied to
7 the sample receiving zone, and instructions for using the
8 device.

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